JAN 2 3 2006

K052680

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of KSEA's knowledge.

Applicant:

Karl Storz Endoscopy-America, Inc.
600 Corporate Pointe Drive
Culver City, CA 90230
(310) 338-8100

Contact: Paul S. Lee

Device Identification:

Common Name:
Holimium (Ho:YAG) Laser

Trade Name: (optional)
Karl Storz CALCULASE Holmium Laser System

Indication: The CALCULASE Holmium Laser System and Accessories are to be used by qualified surgeons in Urological Laser Lithotripsy stone therapy treatment. It is intended to be used in the fragmentation and vaporization of calculi stones in the urinary system (bladder, urethra, and kidney).

Device Description: Karl Storz CALCULASE Holmium Laser System is a Holmium YAG Laser system operating at a wavelength of 2080 (2100) nm with impulse energy of 500-1700mJ and pulse frequency of 4-8Hz. The system is suitable for use in non-invasive and invasive Urological Lithotripsy stone therapy procedures.

Substantial Equivalence: The CALCULASE Holmium Laser System is substantially equivalent to the predicate devices since the basic technologies, designs, safety features, and intended uses are similar. The minor differences between the Karl Storz CALCULASE Holmium Laser System and the predicate devices raise no new issues of safety and effectiveness, as these differences have no effect on the performance, function, or intended use of these devices.

Signed: _____

Paul Lee
Senior Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 23 2006

Mr. Paul S. Lee
Senior Regulatory Affairs Specialist
Karl Storz Endoscopy-America, Inc.
600 Corporate Pointe Drive
Culver City, California 90230

Re: K052680
Trade/Device Name: Karl Storz CALCULASE Holmium Laser System and Accessories
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: September 23, 2005
Received: November 9, 2005

Dear Mr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): Not yet assigned. K052680

Device Name: Karl Storz CALCULASE Holmium Laser System and Accessories

Indications for Use: The CALCULASE Holmium Laser System and Accessories are to be used by qualified surgeons in Urological Laser Lithotripsy stone therapy treatment. It is intended to be used in the fragmentation and vaporization of calculi stones in the urinary system (bladder, urethra, and kidney).

Prescription Use: ✓ AND/OR Over-The-Counter Use: _____
(Per 21 CFR 801Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices
510(k) Number K052680